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TEST AND EVALUATION OF THE SPECTRUM AEROMED, SPECTRUM 500-LP (MILITARY VERSION) MODEL 2500-US

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Final Technical Report for March 1995

AIR FORCE MATERIEL COMMAND
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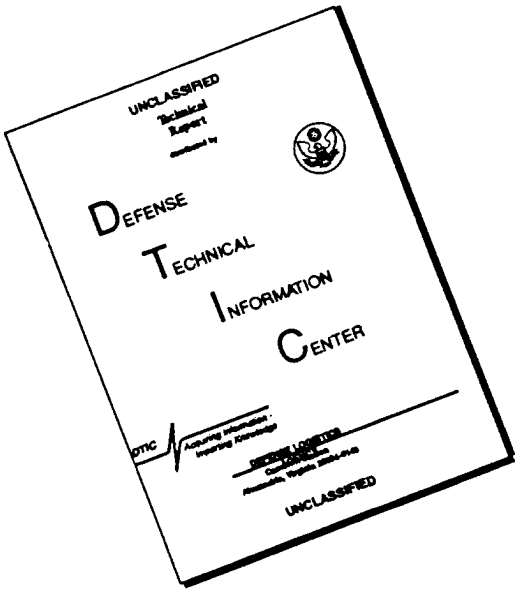

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This report has been reviewed and is approved for publication.

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The Spectrum is a fully modular, quick change air ambulance life support system used in both fixed and rotary wing aircraft. The unit provides 115VAC/60 Hz electrical power, medical air and oxygen, and vacuum.The Spectrums evaluation came at the request of Brig Gen P.K. Carlton, HQ AETC/SG to expand the role of C-21 Learjets involvment in aeromedical evacuation. Aeromedical Research staff members within the Systems Research Branch, considers the unit conditionally acceptable for use in the aeromedical evacuation environment providing all modifications to the unit have been met.

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TESTING AND EVALUATION OF THE SPECTRUM AEROMED, SPECTRUM 500-LP [MILITARY VERSION] MODEL 2500-US

BACKGROUND

At the request of Brig Gen P.K. Carlton, HQ AETC/SG, evaluation of the Spectrum 500-LP Air Ambulance Life Support Unit was initiated. The unit is intended to support aeromedical evacuation needs of Medical Centers who use the C-21 aircraft. Project sponsor is Wilford Hall Medical Center (WHMC). The Spectrum 500-LP is tailored to fit the C-21 aircraft and meet specific component requests from the medical staff at WHMC.

DESCRIPTION

The Spectrum 500-LP Air Ambulance Life Support System is a fully modular, quick change unit for use in both fixed and rotor wing aircraft. The unit automatically locks into place onto a multi-purpose seat rail adapter when placed into position. The unit stretcher is covered with Staph-Chek vinyl over a 2" pad. The unit loading system attaches directly to the unit and is adjustable to various aircraft. Unit specifications are: bench length 72" (182.88cm); width 17" (43.25cm); height to top of bench 10" (25.40cm); height to top of overhead console 40" (101.60cm); standard unit weight 118lbs. (53.1 Kgs); air pump capacity 11 lpm @ 50 psi, vacuum pump capacity 19 lpm @ 14 in.Hg., and 115VAC/60 Hz power is supplied by two 350 watt 28 VDC inverters. A 3,500 L Std., oxygen tank supplys oxygen to the system. Outlets on the overhead console and base unit provide access to oxygen, medical air, and vacuum. The unit also has a heavy-duty telescoping IV pole with 4 hangers holding up to 16 lbs of fluid. See Figure 1. for picture of unit.

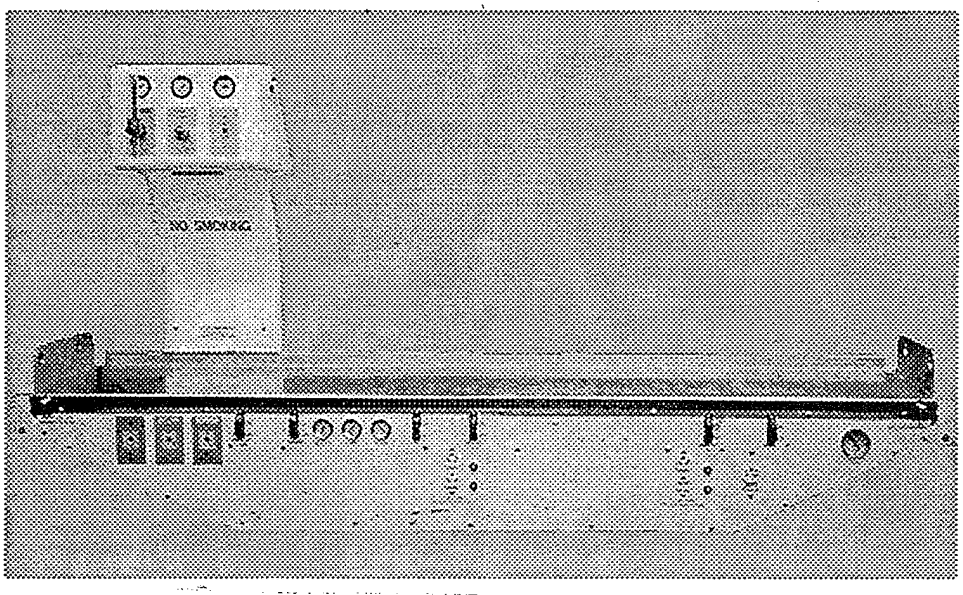

Figure 1. Spectrum 500-LP [Military Version] Model 2500-US.

METHODS

Test methods and performance criteria were derived from various military standards (Reference List, 1-3), nationally recognized performance guidelines (5-7), Spectrum 500-LP User's Guide, Emergency Care Research Institute (ECRI) (4), and Aeromedical Research Procedures Guide (9).

Test Setup

The device will operate from a 28 VDC/25 Amp power supply by way of a pigtail adapter provided by the manufacturer. Oxygen, air, and vacuum flowmeters were inserted into ports on the overhead console and on the base unit. Readings were taken manually from flowmeters, Ohio Intermittent Suction Units (ISUs) and the gauges provided on the device itself. Air flowmeters were set to 15 lpm and Ohio ISUs were set to 200 mmHg by Aeromedical Research personnel. To draw output amperage from the 115 VAC/60 Hz outlets, a network of resistors were plugged into outlets labeled (A) and/or (B) that provided a continuous 3 amp load.

Baseline Performance Assessment

The purpose of the Baseline Performance Assessment (BPA) was to quantitatively measure and record the Spectrum 500-LP's performance under standard ambient conditions before adverse testing. The BPA was used as a reference to measure subsequent performance. It initially verified manufacturer specifications and checked for safe operation before testing. Specifically, the BPA included the following:

Initial inspection. The initial inspection checked for obvious damage to the unit during shipping. It was also an operational verification comparing the Spectrum 500-LP's operating characteristics (i.e., Air & Oxygen gauge pressure, Vacuum gauge pressure) to its numerically displayed parameters. These operating characteristics were measured, recorded, and compared to the manufacturer's published specifications.

Performance Check. The measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. A baseline test consisted of powering the device using a 28 VDC power supply to check the device's internal component readings against manufacturer's and user demand specifications.

A performance check was performed and recorded before and after each laboratory test. During each laboratory test a complete test was done and the parameters were recorded. Values derived from pretest recordings were used as a baseline reference in determining variation in results during each portion of testing. Post-performance check values were used to identify any deviation from the pre-performance check values that might indicate damage to the unit's internal components as a result of testing.

Electrical Safety

Medical Maintenance personnel performed this evaluation to ensure the safety of both the equipment operator and patient. This assessment involved measuring the equipment's leakage current and ground resistance as well as a general inspection of the equipment, IAW AFI's 41-201, 41-203, and National Fire Protection Agency (NFPA) 99 Chapter 19 (5-7).

Electromagnetic Interference (EMI)

Electromagnetic Interference (EMI) testing is a primary concern on all aircraft and is done IAW MIL-STD 461-D and MIL-STD 462-D (1-2). Ensuring the safety of everyone on board is the driving factor to accessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Additionally, the reverse may be true regarding medical devices susceptibility to aircraft emissions, certain frequencies can cause malfunctions to occur to medical devices and/or aircraft electrical systems. Tests included: Radiated Emissions (RE102), Radiated Susceptibility (RS103), Conducted Emissions (CE 102), and Conducted Susceptibility (CS 101, CS 114 & CS 115). During all phases of EMI testing, all components were operated for the duration of the test. Data were taken using Spectrum 500-LP gauges, air flowmeters, Ohio ISUs, and power supply amp meters.

Vibration

These tests are designed to determine an item's durability and performance during worst-case scenario vibrations. The Spectrum 500-LP was subjected to vibration curves with slightly modified levels and lengths from those depicted in Category 10, Figures 514.4-16 and 514.4-17 of MIL-STD-810E (3) (Fig 2). Tests consisted of random (11 to 2,000 Hz) and sinusoidal (5 to 500 Hz) curves on X, Y, and Z axes. During sinusoidal tests, the Spectrum 500-LP was operated and vibrated for 5 sweeps of 15 minute duration (for a total of 75 minutes) on each axis. During random tests, the Spectrum 500-LP was operated and vibrated for 30 minutes on each axis. Before and after each axis, a visual examination of the unit was performed and measurements were recorded.

During vibration testing, the Spectrum 500-LP was secured to the vibration table using the C-21 seat rail adapter specifically designed by the manufacturer for securing the unit to the floor of C-21 (Fig. 3). A special C-21 seat rail simulator was developed to provide a level surface in which to vibrate the unit and to simulate how the device is secured in the C-21 aircraft (Fig. 4).

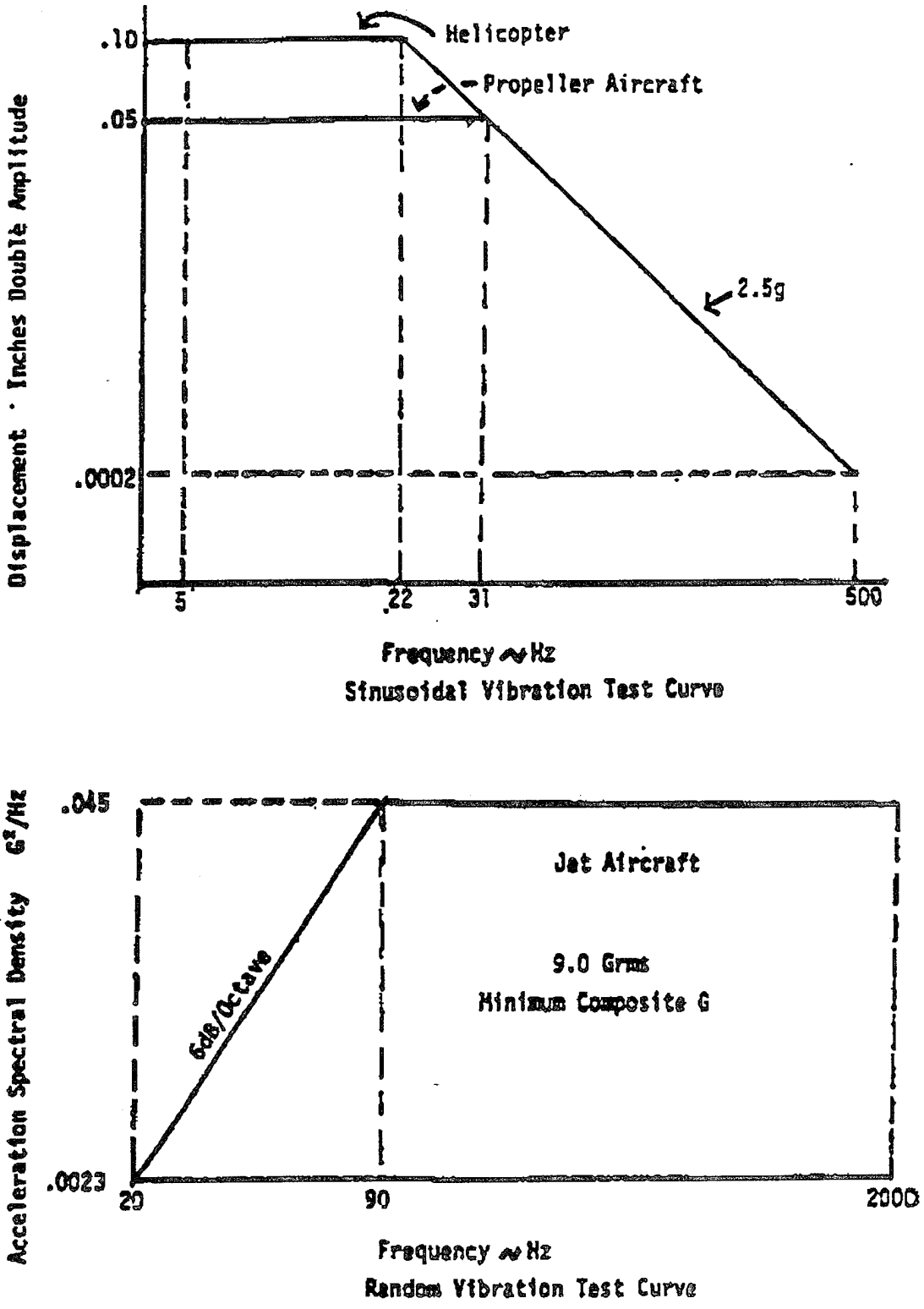

Figure 2. Category 10, Figures 514.4-16 and 514.4-17 of MIL-STD-810E

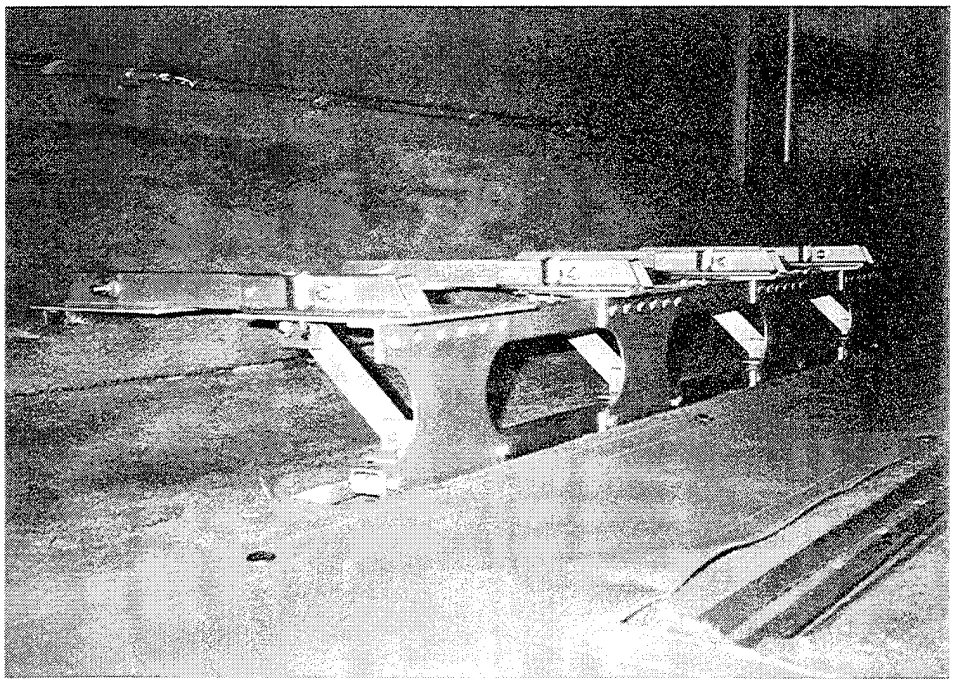

Figure 3. C-21 Seat Rail Adapter.

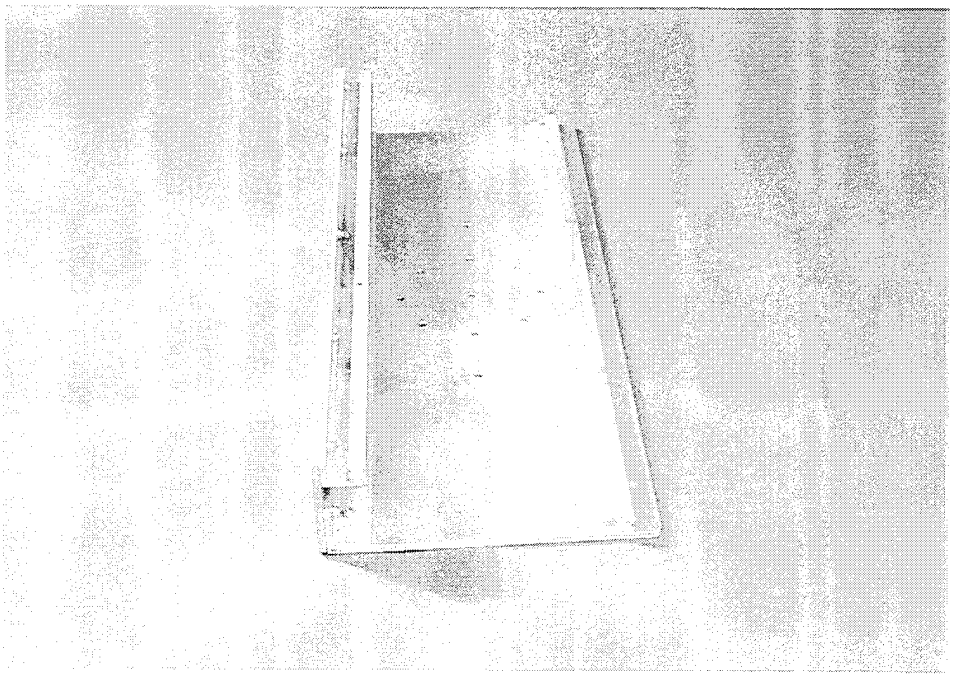

Figure 4. C-21 Seat Rail Simulator

Altitude

The Spectrum 500-LP was tested to determine the effects of reduced barometric pressure in the Armstrong Laboratory hypobaric chambers Brooks AFB TX. The testing consisted of operating the Spectrum 500-LP while connected to a 28 VDC power supply, stopping at 2,000 ft intervals up to 10,000 ft to ensure its continued operation and compliance with prescribed operating parameters. The Spectrum 500-LP was given time to stabilize at each altitude and a complete test was accomplished.

Rapid Decompression

The purpose of this test was to approximate the stress that medical equipment is exposed to during accidental decompression. Although rapid decompressions are uncommon in military transport aircraft, the effects of such an occurrence on a medical item could present a severe safety hazard to the patient, crew, or aircraft operations.

Protocol involved ascending to 8,000 ft at a minimum of 5,000 ft per minute, then decompressing to 40,000 ft in 60 seconds while observing equipment performance. The chamber was returned to ground level and a complete test was accomplished. This test was repeated for seven and one second rates of decompression. The spectrum 500-LP was placed inside the test chamber connected to a 28 VDC power supply. A window was available for visual observation of the pressure gauges, flowmeters, and Ohio Intermittent Suction units to monitor pressures and flows delivered at the time of decompression. The 28 VDC power supply remained outside the test chamber and its amp meter was used to identify power loss experienced by the internal inverters. The unit was reevaluated at the end of each rapid decompression to see if the device returned to baseline parameters.

Environmental

Environmental test conditions were tailored (based on the aeromedical operational environment) from MIL-STD-810E (3). These tests measured the system's performance under varying temperature and humidity conditions encountered during transport. The Spectrum 500-LP was placed inside the environmental chamber. The 28 VDC power supply was set up outside the chamber. At the end of each test, the chamber was dehumidified and the temperature adjusted to 20°C (75°F) to return to existing ambient conditions. The Spectrum 500-LP remained inside the chamber for 30 minutes during this post-test stabilization period, then post-test measurements were taken.

Hot Temperature: Operation: 49° C ± 2° C (120° F ± 3.6° F) for 2 hours.
Storage: 60° C ± 2° C (140° F ± 3.6° F) for 6 hours.

Cold Temperature: Operation: 0° C ± 4° C (32° F ± 7.2° F) for 2 hours.
Storage: -40° C ± 2° C (-40° F ± 3.6° F) for 6 hours.

Humidity: Operation: 94 ± 4 % relative humidity
29.5° C ± 2° C (85° F ± 3° F) for 4 hours.

A complete test was performed prior to starting and at the end of the test period. For operational testing, the unit was evaluated in the chamber while operating from the 28 VDC power supply outside of the chamber. For storage testing the unit was allowed 30 minutes to return to ambient temperature, then a post-test assessment was performed.

Airborne Feasibility

Inflight feasibility tests were conducted to develop and/or verify medical equipment operating procedures and to validate operational performance of the equipment in the actual aeromedical evacuation environment. Inflight testing was conducted on the C-21 aircraft. The Spectrum 500-LP was powered utilizing the aircraft's 28 VDC power supply.

Setup and securing methods, and integration with aircraft electrical systems was evaluated. The flight crew were encouraged to participate in the evaluation and their comments were documented and included in the evaluation.

RESULTS

Electrical Safety

The Spectrum performed within the leakage current guidelines.

Electromagnetic Interference (EMI)

The Spectrum 500-LP was modified to pass EMI-radiated emissions limits and was found to be acceptable for use in the aeromedical evacuation environment. The modified unit will be known as the Spectrum 500-LP [Military Version] model 2500-US. The modifications were: 1) Shielded and shortened internal wires; 2) Filtered input power lines to internal pumps and inverters; 3) Changed circuit breakers and illuminated switches to integral circuit breaker switches.

Vibration

To withstand the rigors of aircraft vibration, the Spectrum 500-LP was modified to pass vibration tests. The manufacturer increased the tensile strength of materials, used stand-offs to avoid air, oxygen and suction lines from rubbing together, and improved securing methods used in mounting the "A" inverter. With these modifications, the unit was acceptable for use in the aeromedical evacuation environment.

Altitude

The air and vacuum pumps were evaluated while delivering maximum outputs. The inverters were tasked to their maximum loading capacity. Some fluctuations in pressure readings were noted during simulated aircraft cabin altitudes. The Spectrum 500-LP performed within acceptable limits.

Rapid Decompression

During all three test parameters, the Spectrum 500-LP maintained therapeutic output levels for both air and vacuum pumps. The inverters supplied maximum source power to 115 VAC 60 Hz outlets.

Environmental

The Spectrum 500-LP operated well during all phases of testing, passing all environmental guidelines.

Airborne Feasibility

This evaluation confirmed that the Spectrum 500-LP will successfully function on the C-21 learjet and is compatible with the aircraft electrical system. To operate the unit on other aeromedical evacuation aircraft specialized securing adapters are required. These adapters can be obtained through the manufacturer. During this evaluation the following was observed.

General observations:

1. Due to interior height restrictions, performing Cardiopulmonary Resuscitation (CPR) may prove difficult. Full arm extension is not possible when performing cardiac compressions.
2. Exercise extreme caution when working within close proximity or passing in front of the base unit. There is a possibility of breaking or dislodging flowmeters, suction devices, and power cords from auxiliary life support equipment.
3. When using more than one Spectrum 500-LP [Military Version], Model Number 2500-US, space limitations will hamper accessibility to egress exits by medical crew.
4. Because of the close proximity of aircraft's passenger seats, visualization of base unit gauges, flowmeters, and suction devices may be difficult.
5. Heat from the metal frame around the light housing on the overhead console may cause a burn injury.

RECOMMENDATIONS

1. Head of bed control lever for raising and lowering patient's head should be located on both sides of the patient stretcher to allow convenient access.
2. Unit will require indoor storage due to exposed electrical outlets.
3. If used on C-9A aircraft, enplane/deplane unit using the patient ramp only. Using the Forward Crew entrance door or aft stairs could result in damage to exposed operating switches.
4. To secure on aeromedical aircraft other than C-21, specialized securing adapter will be necessary. These adapters are available through the manufacturer.
5. Gauges, flowmeters, and suction devices need to be closely monitored due to barometric pressure changes experienced at altitude.
6. Provide covers to protect switches from accidental disengagement and/or breakage.
7. Provide a "stand-off" system of keeping air, oxygen and vacuum lines separated to prevent premature wear.
8. The Ohio Intermittent Suction Unit must be angled 45° to the right to allow connection to the outlet port on the base unit.
9. Have an auxiliary, portable medical air source available when transporting adult ventilatory patients who require blending medical air and oxygen. Unit will not support adult ventilatory patients using 21% blended air from the internal medical air source.
10. Suggest incorporating some type of ventilation around light housing to prevent excessive heat build up, i.e, use a different type bulb, or use a more thermal absorbing material for the frame.

CONCLUSION

Overall, the Spectrum 500-LP [Military Version] model 2500-US, modified to pass EMI radiation limits and vibration curves, is considered airworthy. It operates within expected parameters when subjected to environmental extremes, simulated cabin altitudes, and does not produce a hazard to patient or crew during rapid decompression. However, several human factor concerns should be addressed prior to use in USAF aeromedical evacuation missions.

REFERENCES

1. MIL-STD 461-D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

2. MIL-STD 462 D, "Measurement of EMI Characteristics."

3. MIL-STD 810-E, Environmental Test Methods and Engineering Guidelines.

4. Emergency Care Research Institute (ECRI), INDEX 1993.

5. NFPA 99 chapter 19, "National Fire Protection Agency."

6. AFI 41-203, "Electrical Shock Hazards."

7. AFI 41-201, "Equipment Management in Hospitals."

8. Spectrum Aeromed's Users Guide.

9. Aeromedical Research Procedures Guide, Internal Operating Instruction, Armstrong Laboratory, Systems Research Branch.

APPENDIX A

APPENDIX

SPECIFICATIONS AND OPERATING FEATURES OF THE SPECTRUM 500-LP [MILITARY VERSION] MODEL 2500-US

Model:	Spectrum 500-LP [Military Version] model 2500-US
Manufacturer:	SPECTRUM AEROMED R.R. 2 Box 99 Wheaton, MN 56296
Bench Length:	72" (182.88 cm)
Width:	17" (43.25 cm)
Height:	10" (25.40 cm) to top of bench
Height:	40" (101.60 cm) to top of overhead
Standard Unit Weight:	118 lbs. (53.1 kgs)
Air Pump Capacity:	11 lpm @ 50 psi
Vacuum Pump Capacity:	19 lpm @ 15 in. Hg.
Electrical Supply:	(2) 115 VAC outlets (1) 28 VDC outlet
Inverter:	(2) 350 watt, 115 VAC
Oxygen Supply:	3,500 L.
Dual Pneumatic Supply Outlets:	Oxygen, Medical Air, Vacuum
Spectrum Stretcher:	(US Patent pending)
Spectrum Patient Loading System:	(US Patent pending)
Auxiliary Equipment Table:	4 lbs.
IV Pole:	2 lbs. (.9 kgs) Has four easy pull down hooks for multiple I.V. bags
Quick Release Seat Rail Adapter:	8 lbs. (3.6 kgs)